

# **EXHIBIT A57**

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# Application of weight of evidence and precaution in risk assessment

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## Weight of evidence

A weight of evidence (WoE) approach is a familiar concept found in scientific and regulatory literature. It is generally understood as a method for decision-making that involves consideration of multiple sources of information and lines of evidence. Using a WoE approach avoids relying solely on any one piece of information or line of evidence. Risk assessments of substances conducted under the Canadian Environmental Protection Act, 1999 (CEPA 1999) generally consider multiple lines of evidence to support a risk assessment conclusion (as defined in section 64 of CEPA 1999).

The nature and scope of risk assessments may vary, but all have a WoE component. Assessment approaches may differ depending on the amount and type of data available. Approaches may also differ for the ecological versus the human health assessment of a substance. As a result, the WoE that is considered may differ to some extent with each approach.

A WoE may be applied at various stages of the assessment. It can be used to evaluate the quality of a single study, to assess similar studies for a particular parameter or endpoint, or to integrate information across multiple lines of evidence to support the risk assessment conclusion. Using a WoE involves a number of common steps. In the context of risk

assessments conducted under CEPA 1999, the assessment approach undertaken will determine the details of each step, but generally they include:

1. gathering available and relevant information from multiple sources, including stakeholder submissions of information through voluntary or mandatory surveys, or information requirements for new substances notifications
2. critically assessing the quality or reliability of individual studies or pieces of information, or the sources of summarized information (for example, international assessments)
3. assembling similar information for a parameter or endpoint to develop individual lines of evidence
4. critically assessing each line of evidence based on overall strength or confidence in the information and its relevance to the assessment outcome
5. combining the lines of evidence to characterize risk and reach an assessment conclusion, in consideration of their relative strengths, consistency and coherency.

In conducting an assessment, technical and scientific information may be gathered from sources such as other regulatory bodies and international organizations, the scientific literature, databases, computer models, consultation with experts, and information from stakeholders (see [Information gathering](#)). Relevant data on the substance as well as information on structurally similar substances (called analogues) may be considered in the assessment. The relevant information collected is evaluated and lines of evidence developed to illustrate the risk characterization of the substance; that is, the potential for harm a substance may have in the Canadian environment or on the health of Canadians.

Choices or decisions are made throughout the development of a risk assessment. This may include determining the relative quality of studies, identifying a representative data point for a particular parameter or endpoint, and establishing the significance of each line of evidence. In each case, making a decision involves weighing the relevant information at hand. This is typically done in a qualitative manner, though in some cases could be quantitative. For example, several estimates of a substance's water solubility could be quantitatively weighed as the geometric mean or median, in order to represent the best estimate of its solubility. More complex data or decisions typically involve qualitative weighing of the information or lines of evidence. Qualities of the data are identified (for example, strength and relevance) along with qualitative descriptors (for example, low, medium and high) to help make a decision.

In order to support an assessment conclusion, the significance of the information and relevant lines of evidence are considered to describe the outcome. Where there are multiple lines of evidence feeding into the risk characterization, some qualitative weighing of the strength and relevance of the individual lines of evidence may be done to help integrate the evidence. Greater reliance or weight is placed on stronger and more relevant lines of evidence (including direct evidence for harm or causality and specifically related to Canadian situations). A significant step in the evaluation of the strength of the lines of evidence is the consideration of the uncertainties identified.

## Precaution

Applying precaution in risk assessment means using conservative but realistic assumptions to account for the uncertainty identified at various stages of an assessment. The application of precaution is considered

depending on the WoE and uncertainties for the particular data set being evaluated. For example, a conservative assumption may be made about the percent of a substance that is absorbed through the skin of an organism or human in the absence of data. As another example, a conservative assumption on wastewater removal rates may be used for estimating an exposure concentration in the receiving water.

Precaution is applied at various stages of an assessment, when necessary, to avoid the potential underestimation of risk due to a lack of information, thus erring on the side of being protective of human health and the environment. However, if multiple assumptions are made throughout the assessment, there also needs to be consideration of whether the end result would be a conclusion that is unrealistic. In this case, further refinement of assumptions may be needed, if this is possible. If conservative assumptions have been made but there is no indication of potential risk to either human health or the environment, then further refinement is not needed.

Both WoE and precaution are influenced by uncertainty, thus all three concepts must be considered together in decision-making. A limited low quality data set will increase assessment uncertainty, reduce the strength and likely consistency of the WoE, thereby increasing the need to consider precaution. Conversely, a more robust data set will decrease uncertainty resulting in application of less precaution.

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